Carotid graft replacement: A durable option

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Background: **Carotid artery bifurcation reconstruction after endarterectomy has been refined over the years. Methods including primary closure, patch closure, and eversion endarterectomy have been proven to be durable. However, there are patients who require more complicated reconstructions in primary or recurrent disease management. Carotid replacement with a prosthetic interposition graft is potentially a durable option to reconstruct an artery that is technically unsuitable for primary or patch closure.**

Methods: **The charts of all carotid endarterectomies (n = 482) performed by the authors at our institution between January 1999 and December 2003 were retrospectively reviewed. Follow-up was performed in an Intersocietal Commission for the Accreditation of Vascular Laboratories–accredited vascular laboratory. Patients were divided into two main groups: carotid replacement with 6-mm expanded polytetrafluoroethylene (ePTFE) (REP) or standard endarterectomy (CEA) with or without patch closure. The decision for REP vs CEA (as well as the type of closure) was at the discretion of the surgeon according to an assessment of the end point, the distal internal carotid artery, and the quality and length of the endarterectomy segment. Interposition grafting with a 6-mm stretch of ePTFE from the transected common carotid to the transected internal carotid artery was performed in replacement reconstruction. The external carotid was ligated. Follow-up statistical analyses were performed with the Fisher exact test and analysis of variance for nominal values and *t* tests for continuous variables. Life table analyses were performed for patency and survival.**

Results: **Complete perioperative data were available for 478 of the 482 operations performed (including all REP cases) during the study. At least one duplex ultrasound scan in follow-up was documented in 84% (n = 402) of the patients. A total of 51 were in the REP group, and 427 received CEA (95.3% with patch closure). Preoperative demographics, preoperative symptoms, and degree of stenosis did not vary within the study groups. Three 30-day surgical deaths occurred. The perioperative stroke rate between groups was not statistically different (REP, 1/51 [1.9%]; CEA, 3/427 [0.70%]; $P = .35$). Long-term patency and stroke-free survival rates at 3 years exceeded 96% and did not vary significantly between groups. The presence of a patch in the CEA group had no influence on outcomes. Duplex follow-up scan averaged two studies for at least 14 months in each group. Significantly more REP cases were reoperative procedures.**

Conclusions: **Carotid interposition reconstruction with an ePTFE graft is an acceptable alternative in cases in which the standard technique would be technically difficult or compromising to the endarterectomy closure. Carotid ePTFE interposition graft replacement seems to be safe and durable and to have no increased perioperative risk or altered intermediate-term outcomes. (J Vasc Surg 2005;42:220-6.)**

Carotid endarterectomy is currently widely accepted and practiced for treatment of severe symptomatic and asymptomatic carotid stenosis.[1-3] Technical excellence in the performance of carotid endarterectomy is a prerequisite for optimal results. There are many variables in carotid surgery, including shunting, closure method, type of anesthesia, hemostasis methods, and anticoagulation protocols. Whatever combination a surgeon chooses in performing a carotid endarterectomy, the goal is a disease-free operative site with a technically acceptable reconstruction, a low rate of recurrent stenosis, and satisfactory neurologic outcome.

Because surgeons strive for these goals in every patient, there are situations in which different options might be needed to achieve the desired result. Carotid atherosclerosis can extend further distally into the internal or proximally into the common carotid than initially anticipated. The remnant arterial wall can be less than optimal because of either the plaque or an inadequate endarterectomy. A reoperative endarterectomy site may not have enough quality artery to close. Excess arterial length from tortuosity can interfere with conventional closures. The use of direct inline synthetic interposition grafting for the bifurcation is one way to correct potential problems in achieving the desired reconstruction. The trauma literature[4] is supportive of this approach. The purpose of this article is to review the results of carotid interposition grafting and its use in the treatment of selected patients with conventional carotid atherosclerosis and recurrent stenosis.

MATERIALS AND METHODS

Four hundred eighty-two consecutive patients undergoing carotid reconstruction by the two senior authors (G.N.Y. and H.C.V.) from January 1999 through December 2003 were retrospectively reviewed and grouped with respect to the presence or absence of a carotid interposition graft replacement (REP) vs standard endarterectomy techniques (CEA). The institutional review board at the hospital where the procedures were performed approved this study.

Patients were followed up in an Intersocietal Commission for the Accreditation of Vascular Laboratories–accredited vascular laboratory with interval carotid duplex scans and clinical examinations at 3 months and each year there-

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Competition of interest: none.

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after. Validated criteria for less than 60%, 60% to 79%, 80% to 99%, and probable occlusion were used in this laboratory for the period of the study, thus determining the 60% threshold for recurrent stenosis. Digital subtraction angiography and, in more recent years, computed tomographic angiography were performed of the aortic arch and carotid arteries when hemodynamically significant recurrent stenosis was identified. Antiplatelet therapy (aspirin 325 mg) was standard after surgery unless it was contraindicated or other anticoagulation was mandated for coexisting diseases. Clinical variables that were considered included cardiovascular risk factors, preoperative stenosis and symptoms, and procedural technical factors (Table I). Outcomes assessed included death (both 30-day and long term), neurologic complications, cranial nerve palsies, recurrent stenosis, and other postoperative events (Tables II and III).

Patients were divided into two main groups: carotid replacement with 6-mm expanded polytetrafluoroethylene (ePTFE) (REP) or standard endarterectomy (CEA), with or without patch closure. No vein graft interpositions were used. The decision for REP vs CEA (as well as the type of closure) was at the discretion of the surgeon, according to an assessment of the end point, the distal internal carotid artery, and the quality and length of the endarterectomy segment. The specific reason or reasons for a replacement were not tabulated because of the limitations inherent in a retrospective chart review. Interposition grafting with a 6-mm stretch of standard wall ePTFE from the transected common carotid to the transected internal carotid artery was performed as an inline replacement reconstruction. The graft ends were beveled to match the arterial segments. Monofilament sutures were used with care to avoid any purse-string effect. Shunting was selective, according to carotid stump pressure and clinical presentations. The external carotid was ligated. General anesthesia was standard. All patients received heparin and their anticoagulation was routinely reversed with protamine unless contraindicated. No patient required mandibular subluxation.

Follow-up statistical analyses were performed by using the Fisher exact test and by using analysis of variance for nominal values and *t* tests for continuous variables. Kaplan-Meier life table analyses were performed for patency and survival. In statistical analysis, the presence or absence of a patch (used in 95.3%) in a primary CEA did not influence outcomes, so all nongraft procedures were categorized as one group for the analysis.

RESULTS

Patient historical preoperative data are summarized in Table I. Complete perioperative data were available for 478 of the 482 operations performed (including all REP cases) during the study. At least one duplex ultrasound scan in follow-up was documented in 85% (n = 402) of the patients by using the previously stated validated criteria and the definition of 60% stenosis as a significant recurrence. Preoperative demographics, preoperative symptoms, and degree of stenosis did not vary within the study groups.

Table I. Demographics and clinical characteristics

Preoperative factor	*Standard CEA (n = 427)*	*Graft replacement (n = 51)*	*P* value
Hypertension	71.7%	76.4%	.49
Diabetes mellitus	30.7%	31.4%	.93
Tobacco use	60.0%	72.5%	.08
Asymptomatic	72.6%	78.4%	.37
Significant coronary artery disease history	52.2%	45.0%	.34
Preoperative TIA	15.0%	9.8%	.32
Preoperative stroke	12.4%	7.8%	.35
Age	69.6 y	68.4 y	.40
Side operated on: left	49.6%	54.9%	.48
Sex (% male)	57.8%	52.9%	.51
Redo carotid procedure	1.2%	56.8%	<.00001
Preoperative stenosis	81.3%	80.1%	.42
Patch use in CEA	95.6%	Not applicable	Not applicable

TIA, Transient ischemic event; *CEA*, Carotid Endarterectomy; *REP*, Interposition graft replacement.

Three surgical deaths occurred within 30 days (REP, 1/51 [1.9%]; CEA with patch closures, 2/427 [0.47%]; $P = .20$). The perioperative stroke rate was not statistically different between groups (REP, 1/51 [1.9%]; CEA, 3/427 [0.70%]; $P = .35$). The combined stroke and death rates were also similar (REP, 1/51 [1.9%]; CEA, 5/427 [1.2%]; not significant). All CEA patient morbidity and mortality were in primary, nonredo carotid procedures. The deaths in these patients were from myocardial infarctions. The sole postoperative stroke patient in the replacement group died in the postoperative period from a myocardial infarction, and it is unknown whether that graft had thrombosed. None of the few non–patch closure CEA patients had a stroke or died.

Other perioperative outcomes are summarized in Table II. Long-term patency and stroke-free survival rates at 2 years exceeded 96% and did not vary significantly between groups, as noted in Table III and Figs 1 and 2. Because of the smaller numbers, there was more than 10% SE in the patients 3 years and later in the REP group survival. A significantly higher proportion of reoperative procedures occurred in the REP group. However, the presence of a redo procedure was not significant in outcome differences between the REP and CEA patients when this was subjected to multivariate analysis. No hematomas occurred in the REP patients, and only 5 of the 14 CEA patients with hematomas required re-exploration. The other nine hematomas were noted to be moderate, and no additional patient problems occurred from them.

DISCUSSION

Endarterectomy remains the standard with which all other management of carotid bifurcation disease is compared.[1,2] Investigation of alternative methods, such as carotid stenting, is ongoing with the hope of having a durable option with comparable results for the high-risk patient.[5]

Table II. Perioperative complications and outcomes

Perioperative factor	*Standard CEA (n = 427)*	*Graft replacement (n = 51)*	*P* value
Death—30 d	0.47% (n = 2)	1.9% (n = 1)	.20
Stroke—30 d	0.70% (n = 3)	1.9% (n = 1)	.35
Combined stroke and death—30 d	1.2% (n = 5)	1.9% (n = 1)	.62
TIA—30 d	0.0%	0.0%	NA
Cranial nerve injury—all	2.8% (n = 12)	7.8% (n = 4)	.06
Cranial nerve injury—non–marginal mandibular	1.9% (n = 8)	1.9% (n = 1)	.97
Cranial nerve injury—marginal mandibular	0.94% (n = 4)	5.9% (n = 3)	<.0054
Infection	0.23% (n = 1)	0.0%	.44
Hematoma	3.3% (n = 14)	0.0%	.19
Myocardial infarction (nonfatal)	0.47% (n = 2)	0%	.20

TIA, Transient ischemic event; *NA,* not applicable; *CEA*, Carotid Endarterectomy; *REP*, Interposition graft replacement.

Table III. Long-term complications and outcomes

Follow-up factor	*Standard CEA*	*Graft replacement*	*P* value
Lost to follow-up	14.5% (n = 61)	11.7% (n = 6)	.60
Duration of duplex follow-up scan	15.2 mo	14.7 mo	.78
Average No. of duplex scans per patient in follow-up	2.1	2.2	.83
Recurrent >60% stenosis	3.3% (n = 11)	2.2% (n = 1)	.69
Late death	2.1% (n = 7)	3.9% (n = 2)	.41
Late stroke	0.7% (n = 3)	1.9% (n = 1)	.35
Late TIA	0.0%	0.0%	Not assessable
Late infection	0.0%	0.0%	Not assessable

TIA, Transient ischemic event; *CEA*, Carotid Endarterectomy; *REP*, Interposition graft replacement.

The different closure methods of open endarterectomy have been extensively studied.[6-8] The options include primary closure, patch grafting, and interpositional graft replacement. Factors influencing the choice include the size of the artery, sex, reoperation, technical issues, and surgeon preference.[6-10]

Saphenous vein grafting has proven to be a suitable alternative for reconstruction. Treiman et al[11] reported on 162 carotid reoperations, of which carotid resection with autogenous vein graft replacement was used in 57 patients with results comparable to those with repeat endarterectomy. However, Rockman et al[7] observed a higher rate of late failures when a vein graft or patch was used as compared with any synthetic material (26.7% vs 2.3%). The saphenous vein is popular for harvesting for coronary artery bypass grafting and peripheral vascular uses. Frequently, the saphenous vein can be inadequate or has been previously removed in the management of vascular disease. Synthetic material as a patch has been successfully used in carotid reconstructions for many years with acceptable restenosis and infection rates.[7] Given the ease of use of ePTFE, the lack of necessity for a separate harvest incision, and the frequent lack of vein availability, we started using ePTFE interposition graft reconstruction more readily in difficult cases. In addition, the patients were not routinely prepared for saphenous vein harvest. This factor, combined with evolving comfort and experience with the REP technique, contributed to no vein graft use in this series.

Of the 51 interposition reconstructions in this series, there were 22 (43.2%) primary operations and 29 (56.8%) reoperations. The primary interposition reconstructions were used for difficult anatomy (kinks, coils, and so on), unsatisfactory endarterectomized surfaces, and excessively thin endarterectomized walls where it was believed that standard patch graft closure would yield a compromised result. In redo procedures, many arteries were believed to be inadequate after the original patch closure was resected. The exact indication(s) for patients could not be discerned from the retrospective chart review process. In many patients, multiple reasons were probably important. Several of the cases had heavy plaque longer than 7 cm, with extensive common carotid and internal carotid involvement. Although plication techniques are an excellent method for dealing with anatomic lengthening and tortuosity, it was not believed to be useful in cases in which the plaque burden was also excessive. Again, evolving experience with the replacement technique led to its increasing application over the time of the series reported. Carotid stent angioplasty was not and is still not available at our institution; therefore, no stent cases were included in this series. Patients were not referred away for carotid stenting if they were believed to be at acceptable risk for either primary or redo endarterectomy. One patient with extensive neck fibrosis from prior radiotherapy was referred for evaluation for carotid stenting for a symptomatic stenosis.

Interposition graft reconstruction with synthetic material has been shown to be a durable option in the trauma setting.[4] However, the use of synthetic graft replacement of the carotid bulb has been limited. Sise et al[12] reported on 26 ePTFE graft replacements in 23 patients, with 9 of these

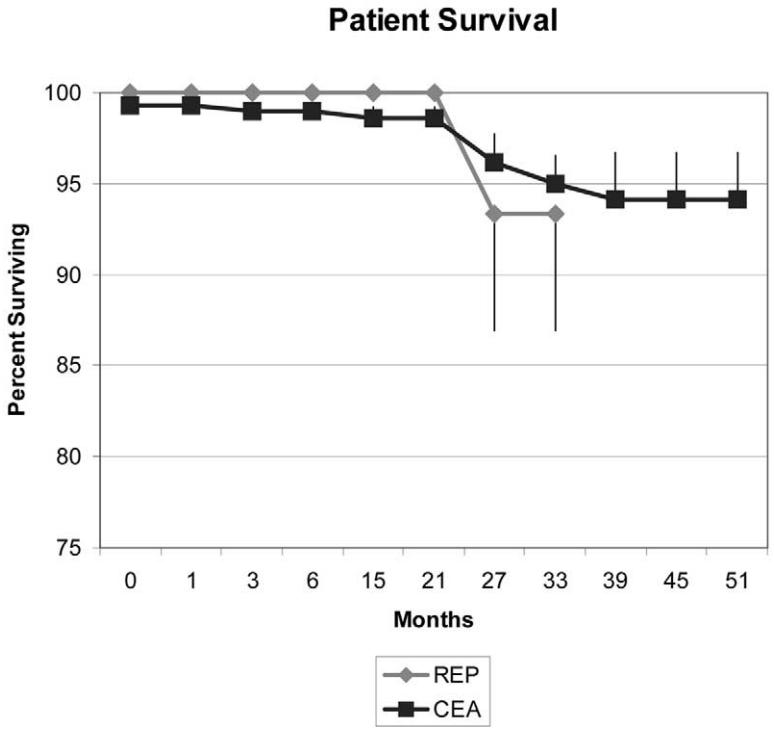

Fig 1. Patient survival life table. Data points end when the SE of Kaplan-Meier analysis exceeds 10%. CEA, Carotid Endarterectomy. REP, Interposition graft replacement.

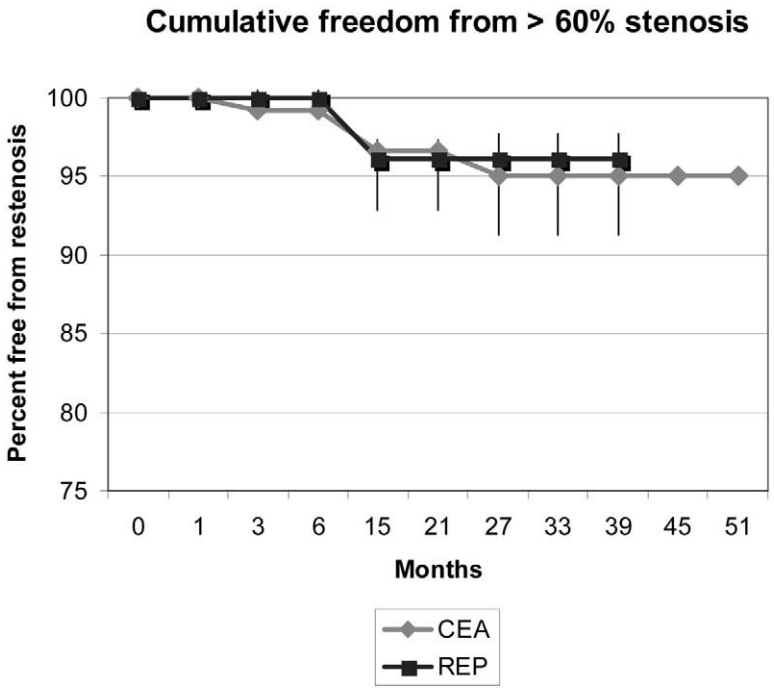

Fig 2. Cumulative freedom from restenosis of 60%. Data points end when the SE of Kaplan-Meier analysis exceeds 10%.

being performed for recurrent carotid stenosis. Sise et al noted an overall restenosis rate of 20%, with a rate of 33% (3/9) in the reoperative group. Our restenosis rate was 2.2% (1/45) in the REP group. The difference may be related to the carotid reconstruction technique. Sise et al preserved the carotid bulb with the proximal anastomosis originating from the bulb, thus preserving the external carotid artery and the carotid contour. Although Sise et al did not mention the sites of restenosis, it may be that their graft originated off of a bulb that was not normal because of previous endarterectomy and that thus had a greater propensity for restenosis. In contrast, this series describes an inline reconstruction with attention to anastomosing proximally and distally beyond areas of disease or previous endarterectomy. The external carotid artery was ligated. If the artery was thickened with atherosclerosis at the proximal end, then focal endarterectomy of the common carotid artery was performed. The single recurrent stenosis in our series was in the distal common carotid artery just proximal to the graft origin.

Cormier et al[13] reported on 62 revascularizations with ePTFE in the carotid position, with neurologic complications in 5% and early postoperative occlusion in 3.2%. Their surgical technique involved long grafts from more proximal inflow vessels. There were 48 grafts from the retroclavicular common carotid artery, 9 from the subclavian artery, and 5 from the ascending aorta. The distal anastomosis was end to side to the internal carotid artery in 54 and was end to end in 8 cases. Although their series represents a longer graft used for different indications, their favorable results supported ePTFE as a reliable substitute. All of our grafts were 6-mm ePTFE and were shorter (generally 4-8 cm) than these long grafts. All were end-to-end anastomoses proximally and distally, thus yielding an inline reconstruction with presumed less turbulent flow. These reconstructions were readily interrogated with cervical duplex scanning. This method of reconstruction may account for the low incidence of thrombosis (0%) and restenosis (2.2%; mean follow-up, 14.7 months). However, no flow profile analysis has been performed to support this concept, and the mean follow-up is relatively short. Despite the relatively short duration of duplex follow-up scanning, our patients underwent more than 2 duplex scans on average in this series (CEA, 2.1 examinations; REP, 2.2 examinations). Certainly, continued duplex scanning follow-up is important in all of our patients, but especially for the REP group, to better understand the potential effect of neointimal hyperplasia.

If shunting was necessary,[14] then an Argyle shunt was used through the graft and extracted through the proximal anastomosis or a small graftotomy. No complications were identified from ligation of the external carotid artery. Three patients had bilateral carotid interposition reconstructions with external carotid exclusion, without adverse sequelae. There were no facial or neck symptoms, and there was no jaw fatigue in any of these three bilaterally treated patients. There are no data in our series about any effect of external carotid preservation. We did not identify any sequelae from our routine ligation of the external carotid.

The interposition technique is straightforward to the vascular surgeon. Interposition graft replacement results in an acceptably low rate of perioperative complications (Table II). The issue of cranial nerve injury was noted, with a slightly higher rate of temporary marginal mandibular palsies in the REP group. Multivariate analysis did not reveal any significant effect of the presence or absence of a reoperative procedure in the REP marginal mandibular palsies. However, the marginal mandibular palsy is typically a retraction injury from the need for high exposure and not from the carotid reconstruction per se. The REP patients were typically selected because of extensive disease in the artery. These patients likely had more extensive superior and inferior exposures. In this series, there was a low rate of cervical hematoma and infection. There was an acceptably low rate of recurrent stenosis in both patient groups over the follow-up period. These patients continue to be followed up with serial duplex examination as much as possible.

Some limitations of our study should be noted. The apparent increase in either stroke or mortality rates alone between REP and CEA patients is accounted for by the fact that it was a single patient in the REP group who both had a stroke and died from cardiac causes. The combined stroke and death rates (CEA, 1.2%; REP, 1.9%) are numerically similar and had no statistical differences. In addition, the average duration of follow-up by duplex scan was only a little longer than a year. Data past 4 or 5 years would be desirable. Many potential indications for a replacement in a redo carotid reconstruction are more intuitive to vascular surgeons. This is especially so if bulky, recurrent disease has to be resected. In a primary carotid procedure, it will be useful to prospectively track indications for graft replacements. Although these issues are important, the data presented still support the replacement procedure as an acceptable technical option for the surgeon. The series presented also seems to represent the largest patient volume with carotid replacement to date.

CONCLUSIONS

Carotid endarterectomy is still a standard of care for many patients with carotid atherosclerosis. Its success over the years is the result of surgeons refining technical aspects to improve patient outcomes. We still believe that conventional endarterectomy with a high rate of patch closure is the first approach to patients with severe carotid atherosclerosis. However, patients exist in whom conventional endarterectomy closure may not leave the desired reconstructed artery. Although this study has limitations, primarily based on its retrospective design and short follow-up, we believe that our data support interposition grafting with ePTFE as a reasonable option for carotid reconstruction in patients with recurrent carotid stenosis or with primary lesions not amenable to standard endarterectomy.

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DISCUSSION

Dr Bruce R. Perler (Baltimore, MD). I want to congratulate Dr Veldenz and colleagues on an excellent series and thank them for getting their very well-written manuscript to me in a timely fashion.

In a sense, they've taken on a tough challenge, namely trying to improve upon a great operation, carotid endarterectomy. I'm not certain that they have achieved that goal, and that's not surprising.

In a series of 478 patients undergoing carotid endarterectomy, they replaced the diseased segment with a PTFE graft in 51 cases, or 11% of the patients. Although the differences were not statistically significant, bypass patients did experience roughly three times the stroke, and four times the perioperative mortality rates of the endarterectomy cases. This most likely reflects the more complex disease in the bypass patients. On the other hand, perhaps it also suggests that one should undertake this strategy very selectively. I was frankly surprised by how often the authors have performed these bypass procedures. I looked back over my experience of roughly 1,000 carotid endarterectomies over the years, and 15 bypass procedures were performed, a rate of about 1.5%. I have three questions for the authors:

1. I was hoping you could elaborate on the decision-making process in performing a formal bypass procedure in these 51 patients. Was this decision made preoperatively in many cases, for example is this now your routine for redo's, or was it necessitated primarily by unexpected technical difficulties at operation?
2. You routinely ligated the external carotid artery, which can be an important collateral source in some patients. Why not reanastomose the external carotid, since this adds very little to the procedure?
3. Finally, you have concluded that this is a durable procedure, yet your mean follow-up is only about 15 months. All of us are aware that PTFE femoral-popliteal bypass grafts do very well for 2 years, and then patency falls off dramatically. Although you have performed end-to-end anastomoses, are you concerned that anastomotic neointimal hyperplasia will ultimately be a problem in grafts to the internal carotid artery, since it is such a small vessel?

I enjoyed this paper and thank the association for the privilege of the floor.

Dr Velendez. I would like to thank Dr Perler for his comments. Certainly, there is a preoperative tendency in the redo patient to do this. In addressing your question concerning where there was three times the mortality and the increase in neurologic morbidity, I would note that the combined stroke and death rates were 1.2% in the control endarterectomies, while it was 1.9% in the replacement patients. This is much less than a three-times-higher rate for replacements compared to endarterectomy. The peripheral nerve injury rate was a little bit higher, but again, that was more the marginal mandibular involved in exposure. The decision making intraoperatively in a primary case is when we do encounter much more extensive disease and there are potentially some technical issues with that endarterectomy. Certainly, I admit one of the patients I ended up replacing was that patient I showed the CT angiogram on where the artery was essentially not salvageable after resection of all that heavy calcified plaque. In a redo situation, we now are comfortable with the procedure and are leaning to the replacement as our first approach.

With respect to ligation of the external carotid arteries, we have seen no sequela with that, and certainly no patients with jaw exercise pain or other adverse events from lack of that collateral. In fact, there are three patients who over the years have actually had both arteries replaced with this technique, and they seem to have no sequela either on clinical exam from ligation of the externals. Sometimes after resection of that bulb and/or interposition of the graft, it is not as easy to make a good reimplantation of the external. Since we have not found any problems, we just have basically come to the conclusion to just ligate it.

And I have to agree with you that our follow-up is still an average of 15 months. These patients at least have had two duplexes, but unlike the femoropopliteal population, where the rate of graft recurrent stenosis is higher after 2 years, this is a much shorter graft. It is a much higher flow situation and it certainly is a different graft than a long piece of prosthetic in a femoropopliteal position. Since we have reviewed the data and prepared the manuscript, we have had more of the duplexes come through, and again, another five patients have entered into 3 years of follow-up and they actually have not had recurrent stenoses with this technique. Certainly, it will require further study.

Dr Mark Friedell (Orlando, Fla). Henry, I think the importance of your paper is just to show that this is a good alternative for those few times when you are in a tough situation. For me, I have

used it 6 or 8 times in the past 10 years. Radiation disease redo's where you have actually done the endarterectomy and you see what you are left with looks worse than what you would have if you put in a PTFE graft. I remember an occasion with one patient, there was very thick plaque going all the way up the internal. There was no apparent end point and my concern was tacking that plaque down as best I could and just getting out of the situation I was in. I put a graft in just like yours, and I have seen these people in follow-up with duplex scans over the past 4 to 5 to 6 years, and none have restenosed. I think the importance for me of your paper is that if you are in a situation where you are unsure of how to proceed, that this is a viable alternative.

Dr Velendez. Thank you for your comments, Mark. We are not trying to say you should do this instead of carotid endarterectomy. We still believe conventional longitudinal endarterectomy with patch closure is our preferred approached, but this has become another tool if we are in a situation where we need to do something else.